Translational Research Working Group

National Cancer Advisory Board

September 20, 2005 Bethesda, Maryland

Ernest Hawk, MD, MPH Office of Centers, Training & Resources DHHS, NIH, NCI, Office of the Director

Medicine's Emerging Transformation

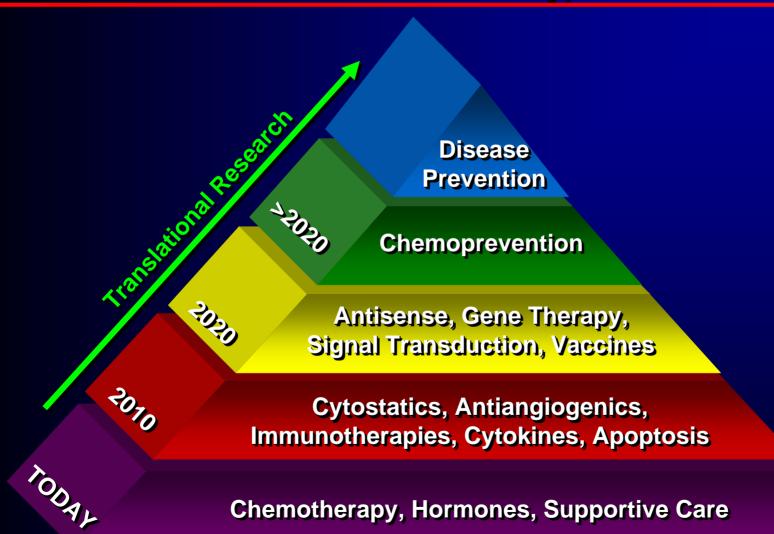


Transition will be fueled by translational science



20th Century	21st Century	Implications
Treat disease when symptoms appear & normal function is lost	Intervene before symptoms appear & preserve normal function for as long as possible	Disease prevention & Health preservation
Cross-sectional, morphologic definition/ understanding of disease	Dynamic, cellular/ molecular understanding of disease processes	Earlier risk identification; more effective, less toxic interventions
Expensive in financial & disability costs	Improved opportunities for effectiveness & efficiency	Greater responsibility to realize the promise

Anticipated Evolution in Cancer Interventions - A View from Industry, 2000



Evolutionary Forces at Play

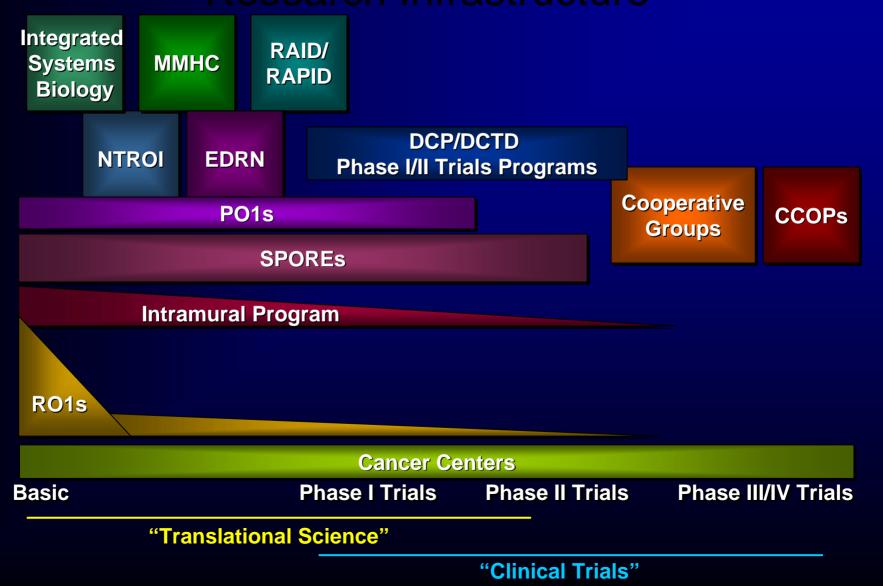
"Negative"

- Behavioral inertia
 - Diet
 - Exercise
 - Chemical abuse
 - Tobacco
 - Alcohol
 - Drugs
- Aging
- Resource limitations
 - Time
 - Money
 - Personnel
- Disorganization

"Positive"

- Molecular insights
 - "omics"
 - Progressively earlier diagnosis
 - Targeted therapies
 - Biotherapies (e.g., vaccines)
 - Shared aberrancies underlying diverse diseases of aging
- Personalized medicine
- Advances in imaging
 - Virtual, serial exams
 - Molecular pathophysiology
- Communication
 - E-records
 - Standardized tools (e.g., ca-BIG)

Components of NCI's "Bench to Bedside & Back" Research Infrastructure



Cancer Centers - Mission

 "To foster excellence in research across a broad spectrum of scientific and medical concerns relevant to cancer"

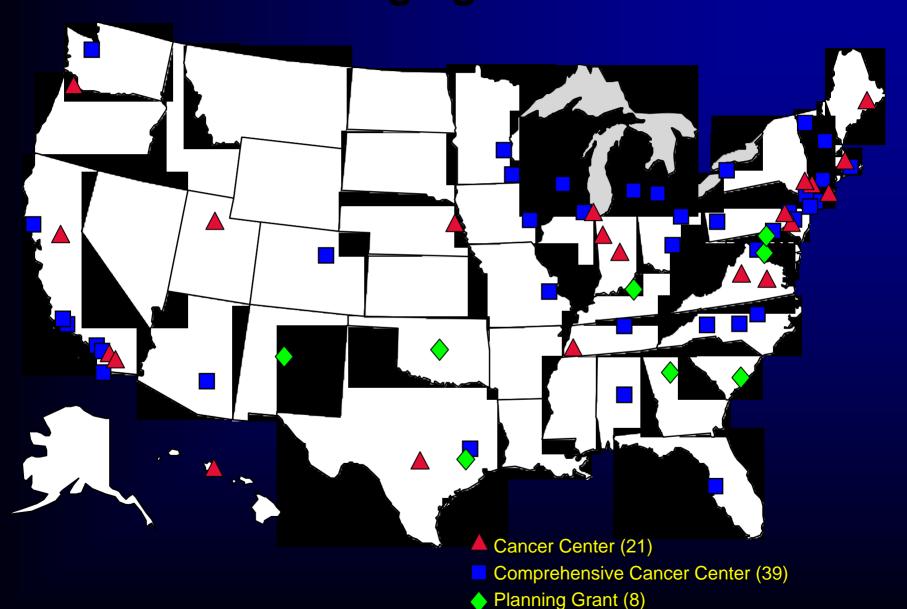
&

 "to extend the benefits of research to patients, their families, and the general public through clinical care, outreach, and education."

Cancer Center Support Grants (P30)

- Essential engines of translational cancer science
 - Currently, 50-60% of all NCI funding goes to NCI-designated cancer centers
- Provide support for research infrastructure & developmental activities
 - Organizational focus and structure
 - Stimulate, organize, and coordinate the competitive cancer research base into interdisciplinary Scientific Research Programs
 - Provide access to quality and cost-effective technologies, services, and scientific consultation to facilitate interactions and enhance scientific productivity

Current and Emerging NCI Cancer Centers



Cancer Centers - Programmatic Questions

Organizational premise

- How can we extend the influence of existing centers beyond their walls?
 - Community
 - State
 - International level
- How can we promote cooperation & coordination?
 - Between centers
 - Between centers and other programs
- How can we address unmet needs in areas without an NCIdesignated center?

Effectiveness

- How effective have new initiatives & supplements been in stimulating the development of emerging scientific areas?
- By what measure(s)?
- What are its greatest strengths/weaknesses?
- How can we improve our databases, activities, interactions?

SPORE (P50) Program

- Mission: To support translational research
- Focuses on developmental science achieving feasibility testing in humans within 5 years – related to
 - Molecular targets
 - Biomarkers
 - Of risk
 - Of interventive response
 - Interventions to modulate risk
- Create networks and consortia to facilitate the translation of novel ideas into clinical interventions

Status of the SPORE Program

Organ Site	2005
Breast	8
Prostate	11
Lung	7
GI	4
Ovary	4
GU	2
Skin	3
Brain	4
H&N	4
Lymphoma	3
Leukemia	1
Myeloma	1
Pancreas	3
GYN	2
Total Programs	57
Total Budget (M)	~\$132 M

SPOREs - Programmatic Questions

Organizational premise

- Organ sites, mechanisms, both, or something else?
- If organs, which should be included/excluded?
- Should it address "less common and/or understudied" (e.g., endometrial, bladder, kidney, esophagus, liver, myeloma) malignancies ...and if so, how?
- How many awards should be allocated per organ, or should scientific merit alone determine allocation?

Effectiveness

- How effective has the program been?
- By what measure(s)?
- What are its greatest strengths/weaknesses?
- How can we improve our databases, activities, interactions?

The Rationale for the TRWG

- Advances in cancer biology offer enormous opportunities to improve public education and clinical practice
 - Earlier, more specific, more definitive assessments of risk
 - Earlier, more effective, less toxic interventions
- Proliferation of NCI programs over the last decade
- Limited resources, unlimited potential, high expectations
 - Time
 - Participants & investigators
 - Dollars
- Important opportunities to accelerate our progress
 - Identify and reduce any redundancies
 - Identify and address unmet needs
 - Facilitate communication
 - Improve coordination

Translational Research Working Group

- National initiative to evaluate the current status of NCI's investment in translational research and envision its future in an inclusive, representative, and transparent manner
- Anticipated Steps
 - Acknowledge prior/concurrent efforts
 - CTWG
 - P30/50 Working Group
 - Progress Review Group reports
 - Define scope of activity
 - Evaluate existing programs
 - Provide vision & recommendations
 - Near-term adjustments of existing programs
 - Long-term vision transcending existing programs
 - Develop implementation strategy

- President's Cancer Panel
- NIH Roadmap initiatives
- NCAB report Cancer at a Crossroads

TRWG Leadership

Lynn Matrisian, PhD

- Vanderbilt University
 - Ingram Distinguished Professor & Chair of Cancer Biology
 - Associate Professor of Obstetrics & Gynecology
- American Association for Cancer Research
 - Past President
- NCI Board of Scientific Advisors
 - Member
- Research molecular carcinogenesis; matrix metalloproteinases and cancer
- Since 2000, funded through R01, P50 (SPORE), R21, T32

William G. Nelson, MD, PhD

- Johns Hopkins University
 - Professor of Oncology, Urology, Pharmacology, Medicine, & Pathology
 - Joint Appointment in Environmental Health Sciences, Bloomberg School of Public Health
- Research focus prostate cancer; cancer prevention & control; therapeutics
- Since 2000, funded through R01, P50 (SPORE), R13

TRWG Strategic Plan

- Announce TRWG plan to NCAB
 - Interact with a variety of interested groups
- Define senior leadership
- Develop membership rosters
 - TRWG & Roundtable invitees
- Share foundational documents
- Develop web-based communication platform
- Initiate translational research outcomes evaluation
- Plan 1st Roundtable and receive public comment on the following topics:
 - What will an optimal translational research program look like in 2015?
 - Elements, focus, leveraging, progress metrics, etc.
 - How can NCI best facilitate that future?
- Convene 1st Roundtable

TRWG Strategic Plan

- TRWG Develop draft model & recommendations based on the 1st Roundtable
- Publicize draft model & recommendations
- Receive public comment
- Convene 2nd Roundtable
 - Discuss draft model, recommendations, and evaluation results
 - Develop a draft implementation plan
- TRWG Finalize an implementation plan
- Present final model, recommendations, & implementation plan to NCAB

Drawing Inspiration from Pasteur

"To the individual who devotes his/her life to science nothing can give more happiness than when the results immediately find practical application.

There are not two sciences. There is science and the application of science, and these two are linked as the fruit is to the tree."

"...chance favors the prepared mind."

"Do not let yourself be tainted with a barren skepticism."